

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

PFIZER INC., PHARMACIA CORP.,	:	
PHARMACIA & UPJOHN INC.,	:	CIV. ACTION NO. 04-754 (JCL)
PHARMACIA& UPJOHN COMPANY,	:	
G.D. SEARLE & CO, G.D. SEARLE LLC,	:	
SEARLE LLC (DELAWARE) and	:	OPINION
SEARLE LLC (NEVADA)	:	
	:	
Plaintiffs,	:	Teva's In Limine Motion No. 7
v.	:	
	:	
TEVA PHARMACEUTICALS USA, INC.	:	
	:	
Defendant.	:	
	:	

LIFLAND, District Judge

This case arises out of Teva Pharmaceuticals U.S.A., Inc.'s ("Teva" or "Defendant") alleged infringement of U.S. Patent Nos. 5,466,823; 5,563,165; and 5,760,068 (the "patents-in-suit"), which are held by Pfizer, Inc., Pharmacia Corp., Pharmacia & Upjohn Inc., Pharmacia & Upjohn Company, G.D. Searle & Co., G.D. Searle LLC, Searle LLC (Delaware), and Searle LLC (Nevada) (collectively "Pfizer" or "Plaintiffs"). The patents-in-suit are directed toward celecoxib, the active ingredient in Celebrex, and a broad genus of compounds that includes celecoxib, pharmaceutical compositions including such compounds, and methods

of using such compounds.

Before the Court is Teva's in limine motion No. 7 to preclude evidence of secondary considerations that are not relevant to the origins of the alleged invention at the time it was made. Teva argues that because the secondary considerations are temporally remote from the time the invention was made, they do "not shed light" on the obviousness of the inventions, which must be evaluated as of "the time the invention was made." (Memorandum in Support of Teva's in Limine Motion No. 7, at 2.) This argument is without merit.

It is well established that secondary considerations, such as commercial success, long-felt but unresolved need, unexpected results, copying, and the failure of others to develop the invention, must be considered as part of a court's obviousness analysis. See, e.g., Glaverbel Societe Anonyme v. Northlake Markeint & Supply, Inc., 45 F.3d 1550, 1555 (Fed. Cir. 1995).¹ Moreover, the Federal

¹ In Graham v. John Deere Co. of Kansas City, 383 U.S. 1 (1966), the Supreme Court noted that secondary considerations "may be relevant in particular cases." Id. at 18. Teva argues, based on this language, that consideration of such evidence is discretionary, not mandatory. The Federal Circuit, however, has clearly instructed that secondary considerations must be considered in every case in which they are present. See, e.g., Custom Accessories, Inc. v. Jeffrey-Allan Industries, Inc., 807 F.2d 955 (Fed. Cir. 1986). "Arguably, the Federal Circuit has more eagerly employed [secondary considerations] than th[e] Supreme Court language [in Graham] would suggest." Roger Schechter and John Thomas, Principles of Patent Law 163 (2d ed.). This Court is bound by the Federal Circuit precedent unless and until the Supreme Court overrules it.

Circuit has made clear that the term “secondary” does not refer to the importance of the considerations, but “instead indicates that these considerations necessarily arise second in time, after the invention has been introduced in the market, in contrast with the other Graham factors which focus upon the ‘time the invention was made.’” Roger Schechter and John Thomas, *Principles of Patent Law* 163 (2d ed.); see also Truswal Sys. Corp. v. Hydro-Air Engineering, Inc., 813 F.2d 1207, 1212 (Fed. Cir. 1987) (“That evidence is ‘secondary’ in time does not mean that it is secondary in importance.”). Accordingly, Teva’s argument that the temporally remote nature of the evidence renders the secondary considerations irrelevant is contrary to well-established law.

Although Teva’s arguments in its in limine motion No. 7 are ostensibly based on this temporal concern, several of Teva’s attacks on Pfizer’s specific evidence of secondary considerations seem to have little or nothing to do with this concern. To the extent Teva’s arguments are based on temporal factors, they are rejected for the reasons explained above. The Court will address Teva’s other, seemingly unrelated, arguments individually.

1. Medical Evidence

Pfizer has indicated that it will introduce testimony that Celebrex’s safety profile is superior to Vioxx and other anti-inflammatories on the market. Teva

contends that this evidence is irrelevant to determining the obviousness of the invention. A showing that an invention exhibits superior and unexpected properties can be indicative of non-obviousness. See, e.g., American Hoist & Derrick Co. v. Sowa & Sons, 725 F.2d 1350, 1360 (Fed. Cir. 1984). However, this Court has ruled that evidence of Celebrex's superior cardiovascular properties does not suggest non-obviousness of the invention and is not relevant to the obviousness inquiry because superior cardiovascular properties were not contemplated as a goal of the inventive process. (See Pfizer v. Teva, No. 04-754, Opinion on Teva's in Limine Motion No. 6, at Part C.2.) To the extent Pfizer seeks to introduce evidence of other benefits of Celebrex over Vioxx and other anti-inflammatories (e.g., decreased gastrointestinal side effects or more effective pain relief) that were contemplated at the time of invention, the evidence is relevant.

Teva also makes a Rule 403-type argument that any relevance of this evidence is outweighed by the delay that would be caused by permitting Pfizer to introduce the "monumental" evidence available on the relative risks of Vioxx versus Celebrex.² The Court disagrees. As explained above, the Federal Circuit

² Federal Rule of Evidence 403 provides: "Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence."

has clearly instructed that evidence of secondary considerations must be considered in every case in which it is present. See, e.g., Custom Accessories, Inc. v. Jeffrey-Allan Industries, Inc., 807 F.2d 955 (Fed. Cir. 1986). Moreover, the Court has already limited the scope of the evidence that Pfizer may present on this issue, thus decreasing the volume of material and amount of time that will be dedicated to the comparative evidence.

2. Licensing

Teva's additional arguments with respect to licensing are a restatement of the arguments set forth in its in limine motion No. 6 with respect to the testimony of Dr. Grabowski. The Court will not repeat its analysis of the issue here. Instead, the Court incorporates the discussion from its opinion in Teva's in limine motion No. 6.

3. Long-Felt Need

Pfizer plans to submit evidence showing that the side effects of non-steroidal anti-inflammatory drugs (NSAIDs) have been well-known for decades, and that researchers have been trying to develop safer NSAIDs since the 1960s. It is well established that such evidence of a long-felt need may be relevant to the obviousness inquiry. See, e.g., Uniroyal, Inc. v. Rudkin-Wiley Corp., 837 F.2d 1044, 1054 (Fed. Cir. 1988). Teva contends that Pfizer's evidence of long-felt

need is irrelevant in this case because (1) the need did not arise until 1991, and (2) “any evidence of a long-felt need bec[ame] irrelevant once the problem to be solved was accomplished by the prior art,” i.e. when Merck filed a patent application that disclosed a COX-2 selective non-steroidal anti-inflammatory drug (“NSAID”) with reduced gastrointestinal side effects. (Memorandum in Support of Teva’s in Limine Motion No. 7, at 8.) As an initial matter, this argument goes to the weight to be accorded to the evidence of long-felt need, not to its admissibility. Moreover, there are problems with both of Teva’s sub-arguments.

With respect to Teva’s first point, Teva argues that “the need” did not arise until the person with ordinary skill in the art would have known about the difference between the COX-2 enzyme (“the inflammatory enzyme”) and the COX-1 enzyme (the stomach enzyme), and the desirability of a COX-2 selective inhibitor. The Court is not persuaded by Teva’s assertion that a long felt need does not arise until the hypothetical person with ordinary skill would have been aware of the specific enzymes involved in solving the problem of NSAID side effects. “[L]ong-felt need is analyzed as of the date of an articulated identified problem and evidence of efforts to solve that problem.” Texas Instruments v. United States ITC, 988 F.2d 1165, 1178 (Fed. Cir. 1993). Pfizer will attempt to show, via the disputed evidence, that the relevant problem was articulated and identified many decades

ago, and that pharmaceutical companies have been making efforts to solve it for nearly as long. This evidence is clearly relevant.

With respect to Teva's second point, the argument is premature. Teva assumes many factual and legal conclusions that have not yet been established. Pfizer disputes that Merck's patent application constitutes prior art. Pfizer disputes that the relevant compound was disclosed by Merck prior to the invention date for the patents-in-suit. Pfizer disputes that Merck solved the problem. Until these issues are resolved, the Court cannot determine how much weight, if any, to accord Pfizer's evidence on long-felt need.

4. Failure of Others

Teva's additional arguments with respect to failure of others are a restatement of the arguments set forth in its in limine motion No. 6 with respect to the testimony of Dr. Galbraith. The Court will not repeat its analysis of the issue here. Instead, the Court incorporates the discussion from its opinion in Teva's in limine motion No. 6.

5. Commercial Success

Finally, Teva argues that evidence of the commercial success of Celebrex is irrelevant because evidence of commercial success has "no force" when a drug's success can be attributed to the five year exclusivity period granted by the Food

and Drug Administration to new chemical entities. Teva relies on Merck & Co., Inc. v. Teva Pharm. USA, Inc., 395 F.3d 1364, 1377 (Fed. Cir. 2005), in support of its argument, but this reliance is misplaced. In Merck & Co., the Federal Circuit explained that the inference of non-obviousness from evidence of commercial success was “weak,” because a “blocking patent” was in place. There is no such “blocking patent” in place here. Moreover, this Court has previously found evidence of commercial success to be probative in cases where the drug at issue was still enjoying the benefits of the five year exclusivity period. See, e.g., Janssen Pharmaceutica NV v. Mylan Pharmaceuticals, Inc., No. 06-6220, Slip op. at 58-59 (D. N.J. Oct. 13, 2006).

Accordingly, for the reasons stated herein, and for the reasons stated in this Court’s opinion in Teva’s in limine motion No. 6, Teva’s in limine motion No. 7 to preclude Pfizer from submitting evidence of secondary considerations that Teva claims is not relevant to the origins of the alleged invention at the time it was made will be denied.

/s/ John C. Lifland, U.S.D.J.

Dated: November 3, 2006